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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,425	02/12/2004	Paul R. Sanberg	1372.129.PRC	4329

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
12/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/777,425	SANBERG ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-12,14 and 16-26* is/are pending in the application.

4a) Of the above claim(s) *19-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-12,14 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2010 has been entered.

Claims 2-4, 13 and 15 have been cancelled, claims 19-26 have been withdrawn from consideration as being drawn to non-elected subject matter, and claims 1, 5-12, 14 and 16-18 have been considered on the merits.

The claim rejection under 35 U.S.C.§112, 2nd par., has been withdrawn due to the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-12, 14 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The newly amended claims disclose the limitation directed to the human umbilical cord blood cell having not been cultured.

The originally filed application does not provide adequate support for the limitation.

M.P.E.P. §2173.05(i) states that any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff 'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993). See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, Waldemar Link, GmbH & Co. v. Osteonics Corp. 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph.

New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter.

Response to Arguments

Applicant's arguments filed 11/12/2010 have been fully considered but they are not persuasive.

Applicant alleged that the disclosure in the specification support the limitation directed to the human umbilical cord blood cell that "has not been cultured".

Applicant asserted that Example 1 discloses that umbilical cord blood was collected and mononuclear cells are isolated, which were washed, counted and suspended in fetal bovine serum and DMSO.

Example 1 of the specification states:

> The remaining cells were spun at 400 g for 10 minutes. 0.5 ml of the supernatant was removed and placed in a pediatric microbiology blood culture tube. The remaining supernatant was removed and RPMI added to the cells. Autologous plasma or fetal bovine serum and DMSO were then added in a drop wise manner to the cord cells and the solution mixed. Aliquot cell suspensions were then placed in sterile cryovials and the samples placed in a controlled rate freezer.

First of all, there is no positive disclosure that the isolated mononuclear cells were not cultured in Example 1. There is no indication that the isolated cells are administered to the target without a culturing step based on this particular disclosure. Example 1 merely discloses how to prepare mononuclear cells from umbilical cord blood, and ho to cryopreserve the isolated

mononuclear cells. The specification is silent about whether or not the isolated cells were cultured prior the administration.

Applicant also referred an embodiment disclosed in the specification that the cells are administered "in the form of intact umbilical cord blood or a fraction thereof", or the cell composition is "without treatment with a mobilization agent or differentiation agent" for the support to the limitation. Applicant interpreted this disclosure as cells not having been cultured.

The Examiner respectfully disagrees with this interpretation because whether or not umbilical cord blood is used as intact or a cell population fractionated thereof, this disclosure does not necessarily mean "without culturing" of the cells in the blood or composition as claimed in the instant claims. The Examiner interprets the term "intact umbilical cord blood" or "a fraction of umbilical cord blood" as without or with isolation of cells from the blood. This does not necessarily mean that the intact umbilical cord blood or a fraction of umbilical cord blood is not cultured. Furthermore, with regard to the disclosure of "without treatment with a mobilization agent or differentiation agent", the Examiner interprets such that these agents are not added to the cell culture medium, and thus the cells are cultured without treatment. In fact, the specification supports the Examiner's interpretation as shown in par. 55:

> The term "differentiation agent" or "cardiac differentiation agent" is used throughout the specification to describe agents which may be added to cell culture (which term includes any cell culture medium which may be used to grow cardiac muscle cells according to the present invention) containing umbilical cord blood pluripotent or multipotent stem and/or progenitor cells which will induce the cells to a more differentiated phenotype, such as a cardiac muscle or muscle phenotype

This paragraph clearly pointed out that these [differentiation] agents may be added to cell culture, and thus, the disclosure of "without treatment with a mobilization agent or

differentiation agent" should be interpreted that without adding a mobilization agent or differentiation agent to the culture medium.

Therefore, it is concluded that there is no adequate support for the limitation of "has not been cultured" as claimed in the instant invention, and thus, this limitation is considered as a new matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651